

REMARKS

This amendment accompanies a Request for Continued Examination (“RCE”).

In response to the final Office action mailed on February 23, 2010, Applicants have added new claims 24-26. Support for new claims 24-26 can be found in, *e.g.*, paragraphs [0025], [0064], and [0065] of the specification, respectively. Claims 1-6 and 16-26 are presented for examination.

Claims 1-6 and 16-23 are rejected under 35 U.S.C. §102(b) as anticipated by, or under 35 U.S.C. §103(a) as obvious from, Shimagaki et al., U.S. Patent No. 6,103,117 (“Shimagaki”).

Independent claim 1 is discussed first. It recites a polysulfone permselective hollow fiber membrane bundle that contains poly(vinylpyrrolidone). The membrane bundle shows a hydrogen peroxide-eluting amount of 5 ppm or less with respect to the mass of the hollow fiber membrane when measured according to the procedure recited in claim 1.

As discussed in Applicants’ response filed on January 22, 2010, the Examiner has not provided any evidence or rationale that the membrane bundles disclosed in Shimagaki necessarily exhibit a hydrogen peroxide-eluting amount of 5 ppm or less with respect to the mass of the hollow fiber membrane. Indeed, given that Shimagaki is entirely silent on any measure that would reduce the amount of hydrogen peroxide in a membrane bundle, it would have been apparent to one skilled in the art that the membrane bundles disclosed in Shimagaki would not necessarily exhibit a hydrogen peroxide-eluting amount of 5 ppm or less, as recited in claim 1. Further, there is nothing in Shimagaki that would have prompted one skilled in the art to modify its process of manufacturing a membrane bundle to reduce hydrogen peroxide therein. Thus, claim 1 is not anticipated or rendered obvious by Shimagaki.

In the final Office action, the Examiner asserts that

The residual hydrogen peroxide - there is no evidence that the reference membrane has residual hydrogen peroxide in an amount more than 5 ppm, or that it will show any more than 5 ppm of hydrogen peroxide when tested using the recited procedure. Applicant has failed to provide any evidence that the reference membrane would have a hydrogen peroxide content of more than 5 ppm,

See page 3, lines 8-13. However, as discussed in Applicant’s January 22, 201 response, the Examiner has not provided any evidence or rationale to support his inherent anticipation rejection in the first place. The Examiner is reminded that

In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from the teachings of the applied prior art.

See MPEP 2112IV. *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) is case on point. In *Ex parte Levy*, Applicant's invention was directed to a biaxially oriented, flexible dilation catheter balloon (a tube which expands upon inflation) used, for example, in clearing the blood vessels of heart patients. The examiner in that case applied a U.S. patent to Schjeldahl which disclosed injection molding a tubular preform and then injecting air into the preform to expand it against a mold (*i.e.*, blow molding). Schjeldahl did not directly state that the end product balloon was biaxially oriented. It did disclose that the balloon was "formed from a thin flexible inelastic, high tensile strength, biaxially oriented synthetic plastic material." *Id.* at 1462 (emphasis added). The examiner argued that Schjeldahl's balloon was inherently biaxially oriented. The Board of Patent Appeals and Interferences reversed the examiner's rejection on the basis that the examiner did not provide objective evidence or cogent technical reasoning to support the conclusion of inherency.

In the present application, the Examiner asserts that Shimagaki inherently anticipates claim 1 simply on the ground that the membrane bundles described in Shimagaki are prepared from the same starting materials. *See* the final Office action, page 2, lines 13-16. Like the examiner in *Ex parte Levy*, the Examiner here has not provided objective evidence or cogent technical reasoning to support the conclusion that, by using the same starting materials as those described in the specification, Shimagaki's process would **necessarily** form membrane bundles having a hydrogen peroxide-eluting amount of 5 ppm or less when measured according to the procedure as recited in claim 1.

In addition, in the January 22, 2010 response, Applicants pointed out the process conditions in the specification that are needed to form the membrane bundle of claim 1. Applicants also pointed out that Comparative Examples 1-3 disclosed in the specification suggest that the membrane bundles described in Shimagaki would **not necessarily** exhibit a hydrogen peroxide-eluting amount of 5 ppm or less in the elution test recited in claim 1. For example, Comparative Example 3 describes a membrane bundle prepared by a process similar to the

process described in Example 6 in Shimagak in that, in both processes, no kneading was performed before preparing a membrane-forming solution and dissolution of the starting materials were not performed in an inert gas. Given that the membrane bundle described in Comparative Example 3 exhibited a hydrogen peroxide-eluting amount of 15 ppm (much higher than that recited in claim 1), one skilled in the art would readily recognize that the membrane bundle described in Example 6 in Shimagaki is highly likely to exhibit a hydrogen peroxide-eluting amount of more than 5 ppm and, therefore, would not anticipate claim 1.

The Examiner asserts that “[t]here is no evidence linking the comparative examples to the Shimagaki hollow fibers.” *See* the final Office action, page 5, lines 3-4. Applicants respectfully disagree. For example, both Comparative Example 3 described in the specification and Example 6 described in Shimagak use the same general process, i.e., forming a membrane-forming solution containing a polysulfone, a polyvinylpyrrolidone, dimethylacetamide, and water and then extruding the solution to form a hollow fiber membrane. Granted, certain process conditions described in Comparative Example 3 in the specification are somewhat different from those described in Example 6 in Shimagaki. However, there is no evidence that these differences are sufficient for the process described in Example 6 in Shimagaki to form a membrane bundle exhibiting a hydrogen peroxide-eluting amount of 5 ppm or less when measured according to the procedure recited in claim 1. Indeed, given that Shimagaki does not realize the need to reduce hydrogen peroxide in a membrane bundle and that it does not use any measure to achieve this specific effect, it would have been apparent to one skilled in the art that the membrane bundles disclosed in Shimagaki would not necessarily exhibit a hydrogen peroxide-eluting amount of 5 ppm or less, as recited in claim 1.

The Examiner is reminded that, according to MPEP 2112IV,

Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.”

In other words, the mere fact that it is possible or even probable that a membrane bundle prepared under some circumstances described in Shimagaki can exhibit a hydrogen peroxide-eluting amount of 5 ppm or less in the elution test recited in claim 1 is not sufficient to establish inherency.

Finally, the Examiner asserts that “[j]ust because the reference does not explicitly teach ... storage stability, it is erroneous to assume that the membrane of the reference would have poor storage stability.” *See* the final Office action, page 3, lines 13-15. However, Applicant did not assume in the January 22, 2010 response that the membrane bundles described in Shimagaki would contain a large amount of hydrogen peroxide and therefore poor storage stability. Rather, Applicants merely pointed out in the just-mentioned response that, given that Shimagaki does not use any measure to reduce hydrogen peroxide in its membrane bundles, its membrane bundles would not necessarily exhibit a hydrogen peroxide-eluting amount of 5 ppm or less, as recited in claim 1, and therefore would not necessarily have good storage stability.

For at least the same reasons set forth above, claim 1 is not anticipated or rendered obvious by Shimagaki. As claims 2-6 and 16-26 depend from claim 1, they also are not anticipated or rendered obvious by Shimagaki. Accordingly, Applicants request reconsideration and withdrawal of this rejection.

Applicants submit that new claims 24-26 are patentable over Shimagaki.

Claims 24-26 depend from claim 1 and, therefore, are patentable over Shimagaki for at least the reasons set forth above.

In addition, claims 24-26 are patentable over Shimagaki on additional, independent grounds. Claim 24 recites a membrane bundle including from 0.5 to 40 mass% of an insoluble matter. Claim 25 recites a membrane bundle having a burst pressure of not lower than 0.5 MPa. Claim 26 recites a membrane bundle having a minimum thickness deviation not smaller than 0.6. Shimagaki does not disclose or render obvious such membrane bundles. Thus, claims 24-26 are patentable over Shimagaki on these additional, independent grounds.

Applicants submit that this application is now in condition for allowance, an action of which is requested.

Any circumstance in which Applicants have: (a) addressed certain comments of the Examiner does not mean that Applicants concede other comments of the Examiner; or (b) made arguments for the patentability of some claims does not mean that there are not other good reasons for the patentability of those claims and other claims.

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The \$1,110.00 fee for the Petition for Three-Month Extension of Time and the \$810.00 fee for the RCE are being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization.

Please apply any other charges to deposit account 06-1050, referencing Attorney's Docket No. 19461-0006US1.

Respectfully submitted,

Date: August 20, 2010

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